

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: ETHICON, INC. PELVIC  
REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION**

**MDL No. 2327**

**THIS DOCUMENT RELATES TO:  
ETHICON WAVE 4 CASES LISTED  
IN EXHIBIT A TO PLAINTIFFS  
MOTION**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE  
THE TESTIMONY OF HARVEY A. WINKLER, MD**

Plaintiffs submit this Reply in further support of their Motion to Exclude Expert Testimony of Harvey A. Winkler, M.D. (Doc. No 3671).

**INTRODUCTION**

Defendants propose to offer into evidence Dr. Winkler's testimony regarding the safety and efficacy of Ethicon's TVT, TVT-Exact, Prolift, and Gynemesh PS products. In their Motion, Plaintiffs demonstrated that Dr. Winkler is unqualified and did not follow a reliable methodology to testify regarding many of his opinions, including the *adequacy* of Ethicon's warnings, the common knowledge of *other* doctors, and the *appropriateness* of Ethicon's corporate conduct.

In its Response, Defendants admit or concede the majority of these fatal flaws. Defendant concedes:

- (1) Dr. Winkler is not qualified to opine on regulatory requirements or whether Ethicon complied with those requirements. Instead, Dr. Winkler admits he did not reliably review the applicable regulatory requirements and instead purportedly "skimmed" the regulations.
- (2) Dr. Winkler has not personally used the TVT-R laser-cut-mesh device and is not aware of a single study comparing TVT-R laser-cut-mesh to TVT-R mechanically-cut-mesh.

- (3) Dr. Winkler admits he does not actually know what other doctors know, what training they received, or what literature they reviewed. Instead, Dr. Winkler admits different doctors have different knowledge.
- (4) Dr. Winkler admits he has no reliable methodology for estimating how many of his patients suffered complications. Instead, he admits he “assumes” his complication rates are the same as what is shown in the literature.
- (5) Dr. Winkler admits he does not have a reliable methodology to assess the extensive body of literature applicable here. Instead, he admits he simply guessed a number in the “middle.”

The Court has consistently excluded doctors from testifying as to many of these subjects. Consistent with previous rulings and the reasoning behind those rulings, Dr. Winkler’s opinions should be excluded here.

## **ARGUMENT**

### **I. DR. WINKLER IS UNQUALIFIED TO RENDER OPINIONS THAT ETHICON ADEQUATELY WARNED AND HAS NOT FOLLOWED A RELIABLE METHODOLOGY.**

Dr. Winkler’s opinions that Ethicon provided *adequate* warnings in its IFUs should be excluded. First, Dr. Winkler is not qualified to offer opinions regarding the regulatory requirements for warnings and admits as much. Second, Dr. Winkler did not employ a reliable methodology to reach these opinions, in part, because he has not actually reviewed the applicable regulations or standards. Therefore, Dr. Winkler’s personal opinions regarding the requirements for warnings are irrelevant, not based on a reliable methodology, and should be excluded. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp 3d 501, 584 (S.D. W. Va. Oct. 17, 2014) (Emphasizing distinction between a doctor testifying as to whether labeling included risks the doctor was aware of and testifying whether labeling was *adequate*).

Dr. Winkler is not qualified to testify on these topics. Ethicon explicitly concedes that “Dr. Winkler is not a regulatory expert.” Defendants’ Memorandum in Opposition at 6 (Doc. No 3784) (“Response”). As the Court has consistently held, an “expert must possess additional expertise to

offer testimony about what information should or should not be included in an IFU.” *See e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 10 (S.D. W. Va. Aug. 31, 2016) (Doc. No. 2701) (Memorandum Opinion and Order – Daubert Motion re: Brian J. Flynn, M.D.) (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202 at \*14 (S.D. W. Va. Feb. 7, 2015)); *see also See Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, \*44 (S.D. W. Va. May 9, 2016) (holding that “without additional expertise in the specific area of product warnings, a doctor, such as a urogynecologist, is not qualified to opine that a product warning was adequate merely because it included the risks he has observed in his own practice.”). Dr. Winkler does not possess such expertise.

Further, Dr. Winkler admits he simply “skimmed” the regulations regarding warnings. Transcript of Dr. Havey Winkler Deposition, 3/12/2017, 8:49 a.m. 198:24-199:7 (“No, I skimmed it.”) (attached as exhibit D to Motion, Doc. No. 3671) (“TVT dep.”). Again, Ethicon concedes this point. Dr. Winkler explicitly testified that his opinions regarding warnings are, in part, based on federal regulations. TVT dep. 206:18-207:2 (“It’s my interpretation of the CFR...”); *id.* 209:19-210:11; Response at 11. Because Dr. Winkler is unqualified and did not reliably review the regulations, Ethicon attempts to rewrite Dr. Winkler’s opinions as *not* based on federal regulations. Of course federal regulations govern product labeling, and Dr. Winkler did not reliably review those regulations.

Dr. Winkler did not follow a reliable methodology or reliably assess the relevant regulations so his opinions regarding the adequacy of Ethicon’s warnings are simply based on his own personal belief and not any reliable objective standard. Accordingly, these and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that “opinion testimony that states a legal standard or draws a legal conclusion by

applying law to the facts is generally inadmissible.”); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013) (excluding testimony regarding legal conclusions such as manufacturer “failed to adequately disclose adverse risks associated with their products” and manufacturer “failed to warn on its label”).

**II. DR. WINKLER IS NOT AN EXPERT IN CORPORATE CONDUCT AND HAS NOT FOLLOWED A RELIABLE METHODOLOGY TO OPINE THAT ETHICON ACTED “APPROPRIATELY.”**

Dr. Winkler seeks to testify regarding his personal opinion as to Ethicon’s corporate conduct. Primarily, Dr. Winkler opines that Ethicon acted appropriate regarding its decision as to when to introduce a new mesh product (TVT-R **laser-cut-mesh**).<sup>1</sup> Ethicon concedes Dr. Winkler is not an expert in corporate conduct. Response at 11. Because Dr. Winkler lacks qualifications to opine regarding corporate conduct, has not reviewed the applicable standards, and has not established that he followed a reliable methodology, these opinions should be excluded.

Dr. Winkler has not cited any regulation or standard to reach his opinion regarding Ethicon’s corporate conduct. Likewise, Dr. Winkler has not established that he reviewed any of Ethicon’s internal standards regarding product development. Dr. Winkler has not established that he has any experience related to corporate conduct. Ethicon simply ignores all of these flaws in its Response. *See* Response 11.

Ethicon argues that Dr. Winkler’s personal opinion as to Ethicon’s corporate conduct is based on his experience *using other mesh* devices. Experience using mesh devices does not necessarily qualify Dr. Winkler as an expert in industry practices or corporate conduct. However, even if personal experience using mesh devices somehow qualified Dr. Winkler on this topic, he

---

<sup>1</sup> Wave 4 Expert Report of Harvey A> Winkler, M.D., Regarding TVT and TVT Exact, February 5, 2017, at 28 (attached as Exhibit C to Motion) (Doc. No. 3671) (“TVT Report”).

still lacks personal experience using the actual device he is opining about. As discussed in Plaintiffs' Motion and conceded by Ethicon, Dr. Winkler has not used the TVT-R laser-cut-mesh product which he opines about. Further, Dr. Winkler admits he is not aware of any study comparing TVT-R laser-cut-mesh to TVT-R mechanically-cut-mesh. His opinion is not based on sufficient facts or data.

Dr. Winkler is unqualified, lacks necessary facts, and has not followed a reliable methodology to reach this opinion regarding Ethicon's corporate conduct. Accordingly, his corporate conduct opinions are unreliable and should be excluded.

**III. DR. WINKLER'S OPINIONS REGARDING TVT-R LASER-CUT-MESH ARE UNRELIABLE BECAUSE HE HAS NO PERSONAL EXPERIENCE WITH THE DEVICE AND ADMITS HE IS NOT AWARE OF ANY STUDIES ADDRESSING THE ISSUE.**

Dr. Winkler seeks to testify that there is no difference in complications or efficacy for TVT-R laser-cut-mesh and TVT-R mechanically-cut-mesh. TVT Report at 7. However, Dr. Winkler has not shown that these opinions are supported by sufficient facts or data. Dr. Winkler has no personal experience using TVT-R laser-cut-mesh. TVT dep. 56:24-57:1; 112:19-21. He also admits there is no scientific evidence directly comparing TVT-R mechanically-cut-mesh to TVT-R laser-cut-mesh. TVT dep. 174:18-19; 173:21-24. The Court has allowed experts to testify regarding the differences between these two devices, when the physician actually has personal experience using the devices. *See In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liabl. Litig.*, 2:12-md-02327, Doc. No. 2668 at 6 (S.D. W. Va. Aug. 26, 2016) (allowing Dr. Rosenzweig to testify regarding differences between mechanical-cut-mesh and laser-cut-mesh because he has extensive experience with both products). However, Dr. Winkler lacks this experience, and his opinions should be excluded.

Ethicon concedes that Dr. Winkler has not used TVT-R laser-cut-mesh and cannot cite any evidence looking at this product. Ethicon is forced to argue that Dr. Winkler's experience using *other* devices and his review of studies involving *other* devices somehow provide a reliable basis for his opinions as to the TVT-R laser-cut-mesh. Response at 12 (discussing Dr. Winkler's experience with TVT-Exact and studies involving TVT-Exact and TVT-Advantage). Of course, different products have different safety and efficacy profiles, based on the unique designs of each product. Dr. Winkler ignores these differences.

Dr. Winkler nor Ethicon has explained how evidence regarding *other* devices can reliably be extrapolated to support his opinions regarding TVT-R laser-cut-mesh. In fact, neither Dr. Winkler nor Ethicon has ever discussed the differences between the TVT-R laser-cut-mesh product and the other products Dr. Winkler has used. More importantly, neither Dr. Winkler nor Ethicon has explained how these different products are so similar that any evidence of one product can reliably be transferred to another product. Without providing any explanation, Dr. Winkler simply assumes evidence and experience regarding other products is applicable here.

Dr. Winkler has no personal experience using TVT-R laser-cut-mesh. Dr. Winkler cannot cite any evidence comparing TVT-R laser-cut-mesh to TVT-R mechanically-cut-mesh. Finally, Dr. Winkler simply assumes evidence regarding other products can be used to support his opinions here. Accordingly, Dr. Winkler does have a sufficient basis and has not established that he followed a reliable methodology, and these opinions should be excluded.

**IV. DR. WINKLER'S PERSONAL OPINION REGARDING WHAT IS "COMMONLY KNOWN" IS NOT THE PRODUCT OF A RELIABLE METHODOLOGY, AND IS NOT BASED ON SUFFICIENT FACTS.**

Dr. Winkler's reports are replete with references to what physicians "commonly know" or "are acutely aware of." See TVT report at 23 ("... surgeons are acutely aware..."); at 35 ("risks

... are commonly known..."); at 41 ("...surgeons are aware...").<sup>2</sup> Unless Dr. Winkler is clairvoyant (something not disclosed on his CV), it is impermissible for Dr. Winkler to offer such speculation under the guise of expert testimony. Dr. Winkler has not established that these opinions are based on sufficient facts or the result of a reliable methodology. Instead, he necessarily admits extensive differences exist between different doctors. Consistent with earlier rulings and because Dr. Winkler has not followed a reliable methodology here, these opinions should be excluded. *See Trevino*, 2016 WL 2939521, at \*39 (excluding opinion that "surgeons are well aware of clinical implications of complications" when expert has not established opinions are the result of a reliable methodology); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 7 (S.D. W. Va. Sept. 2, 2016) (Doc. No. 2727) (Memorandum Opinion and Order – Daubert Motion re: Michael Winkler, M.D.) (The Court has "consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury's fact finding duties.").

Dr. Winkler essentially admits this opinion is unreliable and not based on sufficient facts. Dr. Winkler admits he "can't opine on what people know or don't know." TVT dep. 265:9-10. Dr. Winkler admits different doctors have different knowledge based on differences in training, personal experience, specialties, reading different journals, and attending different medical seminars. TVT dep. 255:9-15; 256:18-23. Additionally, Dr. Winkler admits he has no evidence showing what all doctors are aware of. TVT dep. 267:1-7; Transcript of Dr. Harvey Winkler Deposition, 3/12/2017, 4:10 p.m., 267:1-7 (attached as Exhibit E to Motion, Doc. No. 3671) ("Prolift dep."). Ethicon completely ignores all of Dr. Winkler's admissions.

---

<sup>2</sup> Remarkably, Dr. Winkler even opines as to what *patients* are aware of. TVT Report at 40.

Instead of addressing any of Dr. Winkler's admissions illustrating the unreliability of his opinions, Ethicon spends four pages arguing about qualifications and relevance. Ethicon's lengthy arguments miss the point – the focus here is whether Dr. Winkler's opinions are based on sufficient data and whether his opinions are based on a reliable methodology. Dr. Winkler has admitted he cannot reliably know what other doctors know and has admitted numerous differences exist between different doctors. Ethicon concedes these fatal flaws.

Dr. Winkler has not established that he followed a reliable methodology or that this opinion is based on sufficient facts. Instead, he has admitted numerous differences exist that highlight the unreliability of these opinions. Consistent with the Court's previous rulings, Dr. Winkler's opinions regarding what is commonly known and what physicians are acutely aware of should be excluded.

**V. DR. WINKLER HAS NOT FOLLOWED A RELIABLE METHODOLOGY TO OPINE THAT MESH PRODUCTS ARE AS SAFE AS ALTERNATIVE TREATMENTS.**

Dr. Winkler seeks to testify about the complication rates associated with Ethicon's mesh products and whether those rates are higher than alternative treatments. *See* TVT dep. 291:24-292:5 ("my understanding is that I'm testifying of [sic] whether or not the complication rates are higher with what was commonly known out there and what the rates are as opposed to the absolute rates of the surgical procedure."). Dr. Winkler cannot reliably testify regarding the mesh product **complication rates** if he has not followed a reliable methodology to determine what those rates are.

He states that these opinions are based on his personal experience and his review of the medical literature. However, he concedes the methodology he employed was not reliable. First, he admits he has no reliable method for assessing the complication rates of his own patients. TVT



dep. 116:23-117:4 (“I don’t have a reliable way [to calculate erosion rates.]”); 117:5-10 (cannot calculate rate of dyspareunia); 117:11-17 (cannot reliably calculate rate of chronic pain). Because Dr. Winkler admittedly has no reliable method for assessing the complication rates with his own patients, he admits that any assessment of his own personal experience is simply a “guess.” TVT dep. 116:6-13 (“...Yeah, it’s a guess.”). Therefore, Dr. Winkler is forced to assume his personal experience matches the complication rates in the literature. TVT dep. 115:20-22.

Dr. Winkler’s assessment of the medical literature is also unreliable. A reliable methodology is not automatically assumed by the number of pages or number of citations in an expert report. Instead, the inquiry focuses on whether the expert employed a reliable methodology in assessing the literature. Here, the medical literature contains hundreds of articles with various findings. If Dr. Winkler seeks to testify regarding the complication rates based on the medical literature, he necessarily must establish that he followed some reliable methodology to assess that literature – he has not.

Dr. Winkler cites to numerous findings that are all over the board and somehow concludes the rates are equivalent. Dr. Winkler admits he did not employ any specific methodology to assess the large body of literature. Prolift dep. 58:12-17 (did not perform any statistical analysis to synthesize findings); Prolift dep. 100:14-17; Prolift dep. 100:14-101:2 (cannot be “pinned down to a number” as to the complication rate). Instead, Dr. Winkler’s *only* explanation of any methodology as to how he estimated the complication rates based on the various findings in the literature is that he simply picked “a middle number.” Prolift dep. 98:4-8. This is not a scientific or reliable method.

For Dr. Winkler to conclude that the mesh complication rates are equivalent to alternative treatments or equivalent to complication rates that are “commonly known,” he necessarily must

determine what the complication rates are. How can he reliably compare rates if he does not know what the rate are? He admits he has no reliable method for assessing his own personal experience and instead must rely upon the medical literature. Yet, he refuses to be “pinned down to a number” regarding the complication rates found in the literature. There is simply no reliable explanation as to how he assessed the vast medical literature to reach his vague opinions regarding the complication rates. Accordingly, Dr. Winkler’s opinions regarding the complication rates should be excluded.

**VI. DR. WINKLER’S OPINION THAT MESH DEGRADATION STOPS ONCE THE MESH IS IMPLANTED IS NOT SUPPORTED BY SUFFICIENT FACTS AND SHOULD BE EXCLUDED.**

Dr. Winkler seeks to testify regarding mesh degradation. Additionally, Dr. Winkler proposes to testify that mesh degradation stops once the mesh is implanted. In his deposition, Dr. Winkler admitted he has zero evidence to support this opinion. TVT dep. 176:24-177:18 (“I don’t have any studies that I’m aware of...”). Ethicon argues about other aspects of degradation in its Response, but concedes that Dr. Winkler has no basis for this opinion. For the reasons stated in the Motion, this opinion should be excluded.

**CONCLUSION**

For the reasons discussed above and in Plaintiffs’ Motion, Dr. Winkler should not be permitted to testify as to opinions where he is not qualified, where the opinions are not supported by sufficient facts or data, and where the opinions are the not the product of a reliable methodology.

Respectfully submitted this 4<sup>th</sup> day of May, 2017.

/s/ Joseph J. Zonies

Joseph J. Zonies, Esq.  
Zonies Law LLC  
1900 Wazee Street, Suite 203  
Denver, Colorado 80202  
(720) 464-5300  
(720) 961-9252 fax  
[jzonies@zonieslaw.com](mailto:jzonies@zonieslaw.com)

/s/ Thomas P. Cartmell

Thomas P. Cartmell, Esq.  
Jeffrey M. Kuntz, Esq.  
Wagstaff & Cartmell LLP  
4740 Grand Avenue, Suite 300  
Kansas City, MO 64112  
816-701-1102  
Fax 816-531-2372  
[tcartmell@wcllp.com](mailto:tcartmell@wcllp.com)  
[jkuntz@wcllp.com](mailto:jkuntz@wcllp.com)

/s/ D. Renee Baggett

Bryan F. Aylstock, Esq.  
Renee Baggett, Esq.  
Aylstock, Witkin, Kreis and Overholtz, PLC  
17 East Main Street, Suite 200  
Pensacola, Florida 32563  
(850) 202-1010  
(850) 916-7449 (fax)  
[rbaggett@awkolaw.com](mailto:rbaggett@awkolaw.com)  
[baylstock@awkolaw.com](mailto:baylstock@awkolaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing **PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF HARVEY A. WINKLER, M.D.** on May 4, 2017, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Joseph J. Zonies

Joseph J. Zonies